REMARKS

The Official Action mailed September 30, 2009 has been carefully considered. Reconsideration and allowance of the subject application, as amended, are respectfully requested.

Claims 1-19 and 21-25 were previously pending in the application. Claims 4, 15-19 and 24 are currently withdrawn. Claims 1 and 22 have been amended. No new matter has been added. Claims 1-19 and 21-25 remain under examination in the application.

Applicant and Applicant's Attorney would like to thank the Examiner and her Supervisor for the telephonic interview granted on February 18, 2010. The parties discussed the art of record and appropriate actions for overcoming the pending rejections. These recommended actions are reflected in this Response.

Double Patenting

Claims 1-14, 21-23 and 25 stand provisionally rejected on the grounds of non-statutory obviousness type double patenting over copending U.S. Application Serial No. 10/971,997. The claims in the '997 application have not yet been allowed. Applicant will file a terminal disclaimer in either case upon the allowance of the claims in the other.

Claims 1-14, 21-23 and 25 stand rejected on the grounds of non-statutory obviousness type double patenting over pending U.S. Patent No. 7,169,406. Enclosed is a Terminal Disclaimer to obviate the double patenting rejection over U.S. Patent No. 7,169,406. Withdrawal of the rejection is respectfully requested.

Claims 1-14 stand provisionally rejected on the grounds of non-statutory type obviousness double patenting over pending U.S. Patent Application No. 11/102,454. Enclosed is a Terminal Disclaimer to obviate the double patenting rejection over U.S. Patent Application No. 11/102,454. Withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. § 112

Claims 22-23 stand rejected under 35 U.S.C. § 112 as failing to comply with the written description requirement. Specifically, the Office Action states that the term "VEGF Antagonist" does not have sufficient description in the specification.

The term "VEGF Antagonist" is well understood by those of skill in the art and is commonly used in the patent and scientific literature as a generic term to encompass a variety of compounds capable of interfering with the activity of VEGF. As evidence, an IDS has been filed herewith that includes 10 journal articles that all use the term "VEGF Antagonist" generically to identify compounds that are capable of interfering with the activity of Vascular Endothelial Growth Factor (VEGF). As one of skill in the art would know, at the time of filing, exactly what the term "VEGF Antagonist" means, the written description requirement under 35 U.S.C. § 112 is satisfied. Withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 1, 6-13 and 21 stand rejected under 35 U.S.C. § 102 as being anticipated by Guy Fortier, U.S. Patent No. 5,733,563 (Fortier). Applicant disagrees.

Fortier describes a bioartificial hydrogel that consists of a bifunctionalized polyethylene oxide and an albumin type protein. As amended, claim 1 of the present application recites a hydrogel comprised of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid. Applicant fails to see where Fortier discloses such a hydrogel, as claimed.

With respect to claim 10, the Office Action states that Fortier anticipates claim 10 because Fortier teaches that the hydrogels of the invention are useful for making contact lenses or devices for controlled drug release. Fortier at col. 3, lines 27-30. However, Fortier does not teach that the hydrogel can be used for contact lenses that may also be used to deliver drugs. By using the alternative "or," Fortier fails to make any connection between contact lenses and devices for controlled drug release. Thus, for at least this reason, claim 10 is not anticipated by Fortier.

Claims 6-13 and 21 depend either directly or indirectly from claim 1. Withdrawal of the rejection is respectfully requested.

Claims 1, 6-13 and 21 stand rejected under 35 U.S.C. § 102 as being anticipated by Rajan Bawa, U.S. Patent No. 4,668,506 (Bawa). Applicant disagrees.

Bawa describes a novel hydrogel containing an amino acid as part of the polymer. See Bawa at claim 1.

As amended, independent claim 1 recites a hydrogel comprised of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid. Applicant fails to see where Bawa discloses such a hydrogel, as claimed. Claims 6-13 and 21 depend either directly or indirectly from claim 1. Withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claim 1 stands rejected under 35 U.S.C. § 103 over the combination of Clyde Schultz et al, U.S. Patent Application Publication 2002/0197300 (the '300 application) and Bernard Schwartz, U.S. Patent No. 5,212,168 (Schwartz).

The present application has a priority date of April 9, 2003. The '300 application was published on December 26, 2002, less than one year prior to the April 9, 2003 priority date. As evidenced by the Declaration of Clyde Schultz provided herewith, the subject matter of the '300 application used in the pending rejection was not "by another." Thus, the '300 application is not prior art to the present application. Withdrawal of the rejection is respectfully requested.

Claims 2-3, 5-14 and 21 stand rejected under 35 U.S.C. § 103 over Clyde Schultz et al, U.S. Patent Application Publication 2002/0197300 (the '300 application).

As explained above, the '300 application is not prior art to the present claims. Withdrawal of the rejection is respectfully requested.

Claims 1-3, 6-13 and 21-25 stand rejected under 35 U.S.C. § 103 over Miller et al., U.S. Patent Application Publication No. 2004/0071761 (Miller) in view of Wikipedia (hydrogel article, form 892).

Claims 1-3, 6-13 and 21-25 stand rejected under 35 U.S.C. § 103 over Miller et al., U.S. Patent Application Publication No. 2004/0071761 (Miller) in view of Wikipedia (hydrogel article, form 892).

Claims 22-25 stand rejected under 35 U.S.C. § 103 over Sponsel et al., U.S. Patent Application Publication No. 2004/0198829 (Sponsel).

As Miller and Sponsel are similar in their disclosures, these rejections will be addressed together.

Miller addresses the issue of delivering drugs to the eye by attempting to control the amount of vascular clearance of the drug and by trying to add additional compounds to increase the residence time of the drug. See Miller at paragraph 70. Sponsel attempts to increase the rate of delivery of ocular drugs by including prostanoids to increase the rate of delivery of therapeutic drugs to the eye. See Sponsel at Abstract.

Independent claims 1 and 22 have been amended to recite a hydrogel comprised of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid. Applicant fails to see where either Miller or Sponsel discloses the use of a hydrogel comprised of a tetrapolymer of hydroxymethylmethacrylate, ethylene glycol, dimethylmethacrylate, and methacrylic acid, as claimed. Thus, for at least this reason, neither reference discloses the limitations of the independent claims.

Applicant also notes that each of Miller and Sponsel discuss the difficulty of delivering drugs for the treatment of posterior segment disease. For example, Sponsel states that "Unfortunately, the effectiveness of even the most potent drugs is often limited due to inadequate penetration. In fact, treatment with various drugs is frequently limited on such grounds, particularly where the chemistry of the therapeutic agents renders them less permeable by nature and/or when using drugs of relatively large molecular weight." Sponsel at paragraph 6. Similarly, Miller states that "Delivering therapeutic concentration of drug to the intermediate and posterior ocular region via conventional delivery methods has proven difficult in practice, as the methods are fraught with drawbacks." Miller at paragraph 5. Each of these disclosures attempts to overcome the difficulties of drug delivery by using additional substances to increase the residence time of a drug in the aqueous or by reducing the amount of vascular clearance of the drug of interest. This does indicate a long felt need for a successful delivery mechanism for providing drugs to the posterior segment. However, neither of the references suggests that drugs may be delivered to the posterior segment through a hydrogel placed on the surface of the eye.

As evidence that one of skill in the art would not have combined or modified any of the cited references to arrive at the claimed subject matter, submitted herewith is a declaration by Dr. Eliot Lazar regarding his belief that the results achieved by the Applicant in reaching the posterior segment by placing a hydrogel on the surface of the eye are truly unexpected. Dr. Lazar asserts that one of skill in the art would not have believed that it was possible for drugs to be successfully delivered to the posterior segment via the placement of a hydrogel on the surface of the eye. Thus, one of skill in the art would not have made any effort to combine or modify any of the teachings of the cited references to arrive at the claimed invention.

As further evidence that one of skill in the art would not have expected posterior treatment drugs to be deliverable by a hydrogel placed on the surface of the eye, the Applicant has provided two additional scientific references (in the accompanying IDS) that illustrate the conventional wisdom in the art at the time of filing and even several years thereafter. These references include Eva M. del Amo and Arto Urtti, *Current and future ophthalmic drug delivery systems: A shift to the posterior segment*, Drug Discovery Today, Volume 13, Issues 3-4, February 2008, pp 135-143 (del Amo), and Marvin E. Myles, Donna M. Neumann and James M. Hill, *Recent progress in ocular drug delivery for posterior segment disease: Emphasis on transscleral iontophoresis* Advanced Drug Delivery Reviews Vol. 57, Issue 14, 13 December 2005, pp 2063-2079 (Myles).

Del Amo states that "topical eye drop administration is useful only for the treatment of anterior segment diseases." Del Amo at abstract. In addition, del Amo states that "drops" have "poor ocular bioavailability" and are "ineffective to treat diseases of the posterior segment of the eye." Del Amo at Table 1.

Myles states that "because these diseases are located in the posterior segment of the eye, topical application of ophthalmic medicines is of limited benefit, since topically applied drugs rarely reach therapeutic levels in the affected posterior tissues such as the choroid and retina." Myles at Abstract.

These references, as well as the Lazar declaration and the art of record, show that the topical administration of drugs for the treatment of posterior segment disease was contrary to the accepted wisdom of those skilled in the art. Thus, one skilled in the art would have had no

expectation of success and thus no reason for even trying to deliver drugs to the posterior segment via a hydrogel on the surface of the eye, as claimed. Withdrawal of the rejection is respectfully requested.

Conclusion

Having dealt with all the objections raised by the Examiner, it is respectfully submitted that the present application, as amended, is in condition for allowance. Thus, early allowance is earnestly solicited.

If for any reason the Examiner finds that the claims are not in condition for allowance the Applicant respectfully requests that the Examiner call the undersigned Attorney at 603.668.6560.

In the event there are any fees due, please charge them to our Deposit Account No. 50-2121.

Respectfully submitted,

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